Arguments/Remarks

Claims 23-24, 33-37, and 43 are currently pending. Claims 23, 35, and 37 have been amended to more clearly define the invention. Claims 38-42 have been cancelled. None of the amendments or additional claims constitute new matter.

Rejections Under 35 U.S.C. 112

The claims 35-40 have been rejected under 35 U.S.C. 112, first paragraph as not being enabled by the specification. More particularly, the Examiner states that, "the specification, while being enabling for a method of treating breast tumor comprising the step of administering a compound of formula (I), does not reasonably provide enablement for a method for treatment of neoplastic disease and immune system disorders generally." Applicants have limited the claim to breast tumors, and the rejection is respectfully traversed. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. 102 and 103

The Examiner has rejected claims 23-24, 33-40, and 43 under 35 U.S.C. 103(a) as being obvious over WO03/078404 to Baenteli, et al.

The Examiner however has not applied the obviousness standard correctly, and has not established a *prima facia* case of obviousness. The Federal Circuit recently addressed obviousness of closely-related chemical structures in *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492. F.3d 1350 (Fed. Cir. 2007). Specifically citing their decision of *In re Deuel*, 51 F3d 1552, the Court stated, "A known compound may suggest its homolog, analog, or isomer because such compounds 'often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties'." The Court clarified however, "that in order to find a prima facie case of unpatentability in such instances, a showing that the 'prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention' was also required."

The Court further held in *Takeda*, "Thus in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a

known compound in a particular manner to establish a prima facie obviousness of a new claimed compound."

Still further, the CAFC has further elucidated the obviousness factors for chemical structures in *Eisai v. Dr. Reddy's Laboratories* (533 F.3d 1353) (Fed. Cir. 2008). The CAFC discussed the *Graham* factors in new chemical composition cases, stating, "Post-KSR, a prima facia case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound."

It is therefore necessary that in order to establish a prima facia case of obviousness for a chemical composition of matter, a lead compound must be identified from the prior art, as well as a showing that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.

In the present case, the Examiner has neither identified a "lead compound." The Examiner has however cited example 26 of Baenteli, and indicated that the presently claimed compounds differ from the compounds of Baenteli only because there is a non-hydrogen substituent at the ortho position on the phenyl ring (R10 variable as presently claimed). Applicants have amended the claims to indicate that only one of R7, R8, and R9 may be hydrogen, thus requiring two additional substituents on the ring as compared to example 26 of Baenteli. Although Baenteli has tri-substituted phenyl rings, none of the compounds of Baenteli have a substitution at R10 positon.

Absent such an analysis, the Examiner has not made a prima facia case of obviousness. Withdrawal and reconsideration of the rejection is respectfully requested.

Double Patenting Rejection

The Examiner has rejected claims 23-24, 33-40, and 43 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, and 7-9 of copending applicationo No. 10/507,060, and claims 1-11, and 13-22 of 10/549,250. Upon indication of allowable subject matter, applicants will appropriately address the double patenting rejection.

Should the Examiner have any questions, please contact the undersigned attorney.

Respectfully submitted,

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Date: 1 March 2010